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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ryo Sudo

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,294	Applicant(s) SUDO ET AL.	
	Examiner QUANG NGUYEN, Ph.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/15/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-14 are pending in the present application, and they are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitations "the colony form" and "the position of a pore" in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim. This is because prior to these limitations, there is no recitation of the terms "a colony form" and "a position". Therefore, which specific the colony form of the cultured cells and which particular position of a pore in a permeable sheet do Applicants refer to? For the purpose of a compact prosecution, the examiner interprets these terms as a colony form and a position of a pore in a permeable sheet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-7 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamato et al (WO 02/10349; IDS) (See US 2004/0028657 for the English version).

Yamato et al already disclose at least a method for producing a multi-layered cultured skin sheet, said method comprising the steps of: (a) culturing epidermal cells (e.g., keratinocytes, melanocytes) on a cell culture support having a substrate surface coated with a temperature-responsive polymer whose lower critical solution temperature in water is 0-800C; (b) bringing the temperature of the culture solution to below the lower critical solution temperature; (c) bringing the cultured epidermal sheet into close contact with a polymer membrane; (d) peeling the adhering sheet off together with the polymer membrane; and (e) allowing the epidermal cultured cell sheet in close contact with the polymer membrane of step (d) to adhere to a cell culture support coated with a temperature-responsive polymer, a polymer membrane, other cellular sheet and others; and the polymer membrane in close contact is thereafter peeled off to form multiple culture cell layers (see at least paragraphs 15-19, 29, 38-42 and claims 4-5). Yamato et al also disclosed exemplified temperature-sensitive polymers include homopolymers or co-polymers of (meth)acrylamide compounds, vinyl ether derivatives (paragraph 33); and exemplified polymer membranes include PVDF, polyethylene, cellulose, chitin, chitosan, collagen, polyurethane membranes (paragraph 37). Yamato et al further disclose that the multilayered cultured skin sheet are adapted for use in the treatment of

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a burn or a wound that are gouged deep into a skin tissue in a living body, including a nude rat (paragraphs 20-21, 42, 45 and example 82).

Please note that the above disclosed polymer membranes are permeable sheets, and a multilayered cultured skin sheet falls within the breadth of a three-dimensional tissue or an artificial organ of the present invention. With respect to claims 12-13, by disclosing the use of various polymer membranes such as include PVDF, polyethylene, cellulose, chitin, chitosan, collagen, polyurethane membranes to achieve close contact with the epidermal cell sheet or the multilayered skin sheet, it is a means of defining a colony form of the cultured cells by controlling a position of a pore in a permeable sheet because these various polymer membranes or sheets have different pore positions/sizes.

Accordingly, the teachings of Yamato et al meet the limitations of the instant claims as broadly written. Therefore, the reference anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitaka et al (WO 02/088332; IDS; see US 2004/0073391 for the English version) in view of Germain et al (US 7,521,231).

Mitaka et al disclose at least a method for inducing a liver tissue from small hepatocyte colonies by placing the small hepatocyte-rich colonies onto a sheet of a biocompatible material which is bioabsorbable or biodegradable, and further culturing them for a given period of time (see at least summary of the invention, particularly paragraphs 24, 67-72). Mitaka et al also teach that the biocompatible and bioabsorbable sheets to be used include collagen sheets, collagen sponges, polyglycolic acid sheets (paragraph 69), and the liver tissue thus formed on the sheet can be used for transplantation of the liver as a whole without separating the sheet (paragraph 72). In an exemplification, Mitaka et al observed the formation of bile canaliculi by small hepatocytes seeded on a collagen sheet or a polyglycolic acid felt sheet (example 4).

Mitaka et al do not teach specifically a three-dimensional cell culture method comprising constructing a three-dimensional tissue by stacking cells, including small

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hepatocytes, flat-cultured on a permeable sheet on other flat-cultured cells together with the permeable sheet; and the same three-dimensional tissue construct.

At the effective filing date of the present application, Germain et al already taught a method for preparing a human or animal tissue by applying a compressive force to a stack of sheets of living tissue thereby inducing adjacent layers to fuse or adhere to each other with each sheet of living tissue is comprised of cells and an endogenous extracellular matrix; and the resulting multi-layer tissue construct (thickness of between about 0.01 mm to about 0.5 mm) may comprise between two and twelve sheets of living tissue and the sheets may be of different types (see at least the abstract and Summary of the Invention; col. 3, lines 21-44). Germain et al also teach that multi-layer tissue constructs are thicker and therefore stronger and since multi-layer tissue constructs can comprise more than one sheet of living tissue, they can be designed to more closely resemble the tissues that they intended to replace (col. 1, lines 47-51). Germain et al also disclose that the method utilized cells cultured in vitro as a sheet of living tissue, and utilized cells include adult stem cells, hepatocytes, parenchymal cells and others (col. 3, lines 6-20).

Accordingly, it would have been obvious for an ordinary skilled artisan to modify the teachings of Mitaka et al by also forming a multi-layer liver tissue construct by applying a compressive force to a stack of sheets made of a biocompatible material (e.g., collagen sheets or polyglycolic acid sheets) already seeded with cultured small hepatocyte-rich colonies in light of the teachings of Germain et al as discussed above.

An ordinary skilled artisan would have been motivated to carry out the above modification because Germain et al already teach that multi-layer tissue constructs are thicker and therefore stronger and since multi-layer tissue constructs can comprise more than one sheet of living tissue, they can be designed to more closely resemble the tissues that they intended to replace.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Mitaka et al and Germain et al., coupled with a high level of skill for an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN/

Primary Examiner, Art Unit 1633